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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,554	06/26/2003	Robert M. Brustowicz	CHD-006	5300

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11/02/2005

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EXAMINER

MCCORKLE, MELISSA A

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

7/2/03

Office Action Summary	Application No. 10/606,554	Applicant(s) BRUSTOWICZ, ROBERT M.	
	Examiner Melissa A. McCorkle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 and all subsequent claims, the phrases such as "being of predetermined dimensions and configurations," "predetermined dimensions, configurations, and spatial volume," and "prechosen aligned positions" are indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaillancourt (5,591,138). Vaillancourt discloses an on demand needle retaining and locking mechanism for use in intravenous needle-catheter assembly (fig 3), said mechanism comprising a rotatable on demand needle safety container comprised of an elongated linear shell having at least one discrete wall (fig 3), an open end in said shell adapted for passage there through of a piercing needle (18), an internal spatial volume within said shell sufficient for containing and securing the entirety of a piercing needle (fig 6), a sized tab member (21) disposed on an exterior surface of said shell at a prechosen aligned position adjacent to, but axially removed from, said open end (fig 2), and a plurality of pre-positioned radial and axial cutouts in said wall of said shell wherein at least one of said cutouts is radially positioned and aligned with said tab member (fig 1 and fig 14), and a needle housing unit adapted for mounting upon and axial movement at will over said rotatable needle safety container, said needle housing unit being comprised of a casing (fig 9 and fig 10), a flash chamber for holding one end of a piercing needle (fig 29 and fig 27), and a guide member sized for aligned radial movement at will into and out, said radially positioned cutout for aligned axial movement through said axial cutout in said wall of needle safety container (fig 13), a hollow collar contiguously aligned with and rotably attached to an open end of said linear shell (fig 7, 8, 30)), said rotatable collar having at least one wall (fig 8), having two open ends adapted for passage therethrough of a piercing needle (fig 30), a solid tab member which is disposed on an exterior surface of said wall (fig 3) and at least one pre-positioned radial cutout in said wall which is radially positioned and aligned with said solid tab member (fig 3).

6. Vaillancourt shows the needle-catheter assembly as stated above, wherein said radially positioned and aligned cutout comprises at least one contoured slot (fig 3 and fig 14), and wherein said pre-positioned cutouts include at least one axial groove which is linearly aligned for passage of said guide member (fig 14 and fig 3), wherein said needle housing further comprises a configured spool section comprising a tab-engagement segment and at least one sized notch for on demand engagement (fig 1-5) with said tab member of said needle-safety container, said spool portion being alignable at will with said tab member and being able to engage, retain, and disengage said tab member of said needle-safety container on demand (fig 3) and an extended body section (17), wherein said configured spool section includes a pair of sized notches (fig 3).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Altschuler (5,318,547) discloses a sheathed hypodermic needle; Luther (5,569,217) discloses a percutaneous port catheter assembly and method of use; Ducharme et al (5,000,740) discloses a catheter with needle guard; D'Amico (5,429,613) discloses a self-recapping injection needle assembly; Swensen et al (2003/0125677) discloses medical needle assemblies; and Caizza et al (2003/0125675) discloses medical needle assemblies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle
Examiner
Art Unit 3763

MAM
10/26/05



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